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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/909,573      | 07/20/2001  | Andreas Kaplan       | 1-15407             | 2213             |

7590

03/10/2003

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EXAMINER

KUMAR, SHAILENDRA

ART UNIT

PAPER NUMBER

1621

DATE MAILED: 03/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/909,573

Applicant(s)

Kaplan et al

Examiner

Shailendra Kumar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jul 20, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☒ Claim(s) 11-14 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some\* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6 6) ☐ Other:

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### **DETAILED ACTION**

Claims 1-14 are pending in this application.

#### ***Priority***

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

#### ***Information Disclosure Statement***

2. The information disclosure statement filed 2/5/02 complies with 37 CFR 1.98(a)(3) and has been placed in the application file, the information referred to therein has been considered.

#### ***Claim Rejections - 35 U.S.C. § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over della Valle et al(US 5,506,224).

Instant claims are directed to beta-hydroxyalkylamide of the general formula (I) of claim 1, wherein R2 can be linear or branched alkyl, and R1 can be hydrogen or alkyl.

US' 224 teaches structurally similar compounds as claimed herein. See column 3, lines 55-60, and column 4, lines 42 to column 5, line 2. Note R1-CO can be acyl group derived from the benzoic acid, see column 5, line 1-2, and NR2R3 is formula of line 45 in column 4. The difference between the reference and herein claimed compounds is that the reference has not made any compounds wherein R1-CO is benzoyl and NR2R3 is structure of line 45, column 4.

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It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to obtain compounds within the generic structure of the reference, especially when R1-CO is benzoyl and NR2R3 is structure of line 45, column 4, thus obtaining compounds similar to claimed herein, with the reasonable expectation of achieving a successful pharmaceutical composition for treating autoimmune pathologies, absent evidence to the contrary.

6. Claims 4-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,506,224.

Instant claims are directed to a process of preparing beta hydroxyalkylamide, by reacting an alkanolamine with carboxylic acid derivative, at about -10 to 25° C.

US'224 is teaching an analogous process of making beta hydroxyalkylamide by reacting an alkanolamine with carboxylic acid derivative similar to herein, for example, see examples 8 and 9 in column 9-10 and example 13 in column 11-12. The difference between the reference and herein claimed process is that the reference has not made any compounds wherein R1-CO is benzoyl and NR2R3 is structure of line 45, column 4.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the process of US'224, by reacting , benzoyl chloride or acetate, with alkanolamine, because the process is analogous, and the process condition are similar, with the reasonable expectation of achieving a successful process of obtaining compounds of the instant

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claims, absent evidence to the contrary. Note various examples wherein, structurally similar reactants are reacting, for example in examples 8, 9, and 13.

7. Claims 11-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to S.Kumar whose telephone number is (703)-308-4519. The examiner can normally be reached on Monday to Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached on (703) 308-4519. The fax phone number for the organization where this application or proceeding is assigned is (703)-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-1235.

S.Kumar

3/4/03



SHAIENDRA KUMAR  
PRIMARY EXAMINER  
GROUP 1200